

REMARKS

Supplemental to the Amendment filed October 10, 2007 Applicants are submitting a Second Declaration by Mr. Ohkuma.

In this Declaration, Mr. Ohkuma looked at the stability over time between hydroxypropyl cellulose (HPC), hydroxypropyl methylcellulose (HPMC) and methylcellulose (MC).

At the end of a week the claimed HPC showed that about 95% bFGF remained whereas with both MC and HPMC less than 88% bFGF remained, namely 87.6% and 85.5%, respectively.

This is a significant difference. As explained at page 6 of the declaration ICH Guideline Q1A 2.2.7.1 defines a change of more than 5% change from the initial content in the drug product stabilization test as a "significant change." Additionally, as also explained at page 6, the standard content of a medicament should typically be at least 95% of that standard content. Only the use of HPC achieves these results.

As explained at page 2 of the specification bFGF is physiochemically unstable. Applicants also taught that it was desired to have a preparation where bFGF can be maintained stably so that low amounts of the bFGF can be used to coat a desired surface. The Declaration by Mr. Ohkuma shows that the HPC accomplishes this. By contrast the MC and HPMC do not achieve this objective. As discussed in the main response, particularly regarding Finkenaure, one would have expected equivalent results with HPC, MC and HPMC from the prior art. However, that is not what occurred, thereby establishing the unexpected superiority of HPC.

In view of the foregoing, Applicants respectfully submit that all claims are in condition for allowance. Early and favorable action is requested.

Date: November 5, 2007

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Respectfully submitted,

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